Author's response to reviews

Title: Metformin efficacy and safety for colorectal polyps: A double-blind randomized controlled trial

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Author's response to reviews: see over
Dear Editors,

We enjoy reading BMC Cancer for the information it contains on both clinical and research topics. We would like to re-submit the manuscript, entitled “Metformin efficacy and safety for colorectal polyps: A double blind randomized controlled trial” for publication in BMC Cancer as Study Protocol. I have made the necessary corrections, described in detail in the following.

1) Ethical and Fundings Proofs - As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, please clarify whether you have ethical approval and external funding for your study. If you do, please send evidence of your approvals to us by email. Proof of external funding should include details of the amount of funding that was awarded for your study. Please also provide a list of any manuscripts that are under submission with other journals based on this study protocol.

Reply

We obtained approval for this study from the Ethics committee of Yokohama City University Hospital on July 8th 2011 and described it in page 5. Also we uploaded proof of ethical approval.

We obtained external funding of A Grant-in-Aid for research on the Third-Term Comprehensive Control Research for Cancer from the Ministry of Health, Labour and Welfare, Japan (A. Nakajima), and described it in page 12. Also we uploaded proof of external funding.

2) Trial Registration Number - We notice that you are reporting a clinical trial but have not cited a trial registration number. This must be obtained before we can begin peer review of your manuscript.
BioMed Central has always supported initiatives to improve the performance and reporting of clinical trials, part of which includes prospective registering and numbering of trials. BioMed Central requests a trial registration number for manuscripts reporting work that falls within the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial: any research study that prospectively assigns human subjects to one or more health related interventions to evaluate the effects on health outcomes.

We would like you to confirm that your clinical trial is in a publicly accessible registry before we begin peer review. The trial registration number should be included as the last line of the abstract of the manuscript.

Reply
This trial has been registered in the University hospital Medical Information Network (UMIN) Clinical Trials Registry as UMIN000006254, and we described that in abstract and page 5. Also we uploaded the detail of the registry.

3) Author's Contribution - In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

Reply
We described author’s contribution in page 12 and 13.

I would like to thank helpful comments. Metformin is a biguanide derivative that has been long and widely used for treating diabetes mellitus. Recent study reported that patients with type2 diabetes taking metformin might be at a lower risk of cancer (including CRC) compared with those patients who do not take metformin. We conducted a prospective randomized control trial to evaluate the chemopreventive effects and drug safety of metformin against metachronous colorectal polyps in nondiabetic post-polypectomy patients. We believe that many physicians will be interested in our research. We hope that you will find out our article suitable for your esteemed journal.
Yours sincerely,

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